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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,979

02/18/2005

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1725

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EXAMINER

KIM, ALEXANDER D

ART UNIT

PAPER NUMBER

1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/524,979

Applicant(s)

TAKEMORI ET AL.

Examiner

Alexander D. Kim

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/05/2005, 02/18/2005</u> | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (mailed on 12/18/2006), Applicants filed a response received on 02/06/2007. Claim 34 is pending in this instant Office action.

Election

2. Applicant's election without traverse of Group XXXI, Claim 34, drawn to a method of using a vector comprising a polynucleotide SEQ ID NO: 1 encoding a polypeptide SEQ ID NO: 2 and its host cell. Claim 34 will be examined herein.

As noted in previous office action, the claims will be examined only to the extent they read on the elected subject matter, which is a method regarding SEQ ID NO: 1 and 2.

Priority

3. The instant application is a 371 filing of the International Application No. PCT/JP03/10535 filed on 08/20/2003. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes both a search report and a preliminary examination report.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in 2002-2400092 (Japan, filed on 8/21/2002) and 2002-23295 (Japan,

filed on 1/31/2003). It is noted, however, that applicant has not filed a certified copy of the 2002-2400092 (Japan, filed on 8/21/2002) and 2002-23295 (Japan, filed on 1/31/2003) application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

4. Information disclosure statements (IDS) filed on 02/18/2005 and 10/05/2005 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Claims to foreign applications are missing. Appropriate correction is required.

Compliance with Sequence Rules

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. 1.821 through 1.825; Applicants' attention is directed to the

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final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

The Figure 1A, 1B contains polypeptide without SEQ ID NOs.

The polypeptide in page 124, line 1, is missing appropriate SEQ ID NO.

Labeling using a SEQ ID NO. must be inserted into the brief description of the drawings or into the Figure directly for rat SIK1 protein and human SIK2 protein.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID No.

Objections to the Specification

7. The specification is objected to because of the following informalities:

a. The specification is objected to because the title is not descriptive of the claims.

A new title is required that is clearly indicative of the invention to which the claims are drawn (see M.P.E.P. § 606.01). The examiner suggests the following new title, for example:

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---A method for screening a compound capable of promoting or inhibiting the activity of slat-inducible kinases 2.---

b. The Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source of polypeptides (*Mus musculus*) for completeness.

c. The specification is objected because it does not recite all SEQ ID NOs filed in the sequence listing. The specification is confusing without such disclosure because it is unclear why said SEQ ID NO: 13-15 are included in the sequence listing. Appropriate clarification is required.

Objections to the Drawings

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

The amino acids inside the black box in Figures 1 cannot be deciphered.

The Figures of 10, 14, and 16 shows pictures that is blacked out, which is unable to tell the difference(s) between them.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Color Drawings

9. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted

Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification: The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37CFR 1.84(b)(2).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites the limitation "the activity of a polypeptide" for an activity of SEQ ID NO: 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear if the claims are limited to the one specific activity or to any other activity of SEQ ID NO: 2. Clarification is required.

Claim 34 recites the limitation of "under the control of a cAMP responsive element". However, it is unclear if the polypeptide, a reporter gene or both are under the control of a cAMP responsive element. Clarification is required.

Claim 34 recites the limitation of "or a salt thereof". It is unclear if the salt thereof is referring to the salt of a compound, a vector, a polynucleotide or a polypeptide in the claim. It is thus unclear how "or a salt thereof" effects the scope of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 34 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim 34 is drawn to a method for screening a compound capable of promoting or inhibiting the activity of a polypeptide comprising method steps of: allowing an expression vector and reporter gene under cAMP responsive element to contact with a test compound; and detecting a change in activity of the polypeptide, wherein the vector encoding a polypeptide having at least 90% of substantially identical to SEQ ID NO: 2 or a polypeptide encoded by the cDNA capable of hybridizing to the nucleotide sequence of SEQ ID NO: 1.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."

University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

To fully describe a genus of genetic material, which is a chemical compound, applicants

must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical Inc. v. Gen-Probe Inc.* (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from *Enzo Biochemical* (see above).

Claim 34 is drawn to a genus of method comprising utilization of any polypeptide having any degree of identity by the broad and reasonable interpretation of "substantially identical" to SEQ ID NO: 2. The said polypeptide includes as small as any two consecutive amino acids (i.e. sequence) within the entire SEQ ID NO: 2. The said polypeptide also includes all possible two consecutive amino acids encoded by a DNAs [i.e., any possible 6 consecutive nucleotide (the hexamer)] because any hexamer is capable of hybridizing to the SEQ ID NO: 1 under a certain condition.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only one representative species of the genus (i.e., SEQ ID NO: 2) and only these said polypeptides can be used in assay or test shown in the instant Examples. The specification fails to describe any additional representative species of the claimed genus. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "for inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". In the instant case, the claimed method of utilizing a genus polypeptide comprising any sequence having at least 2 amino acids from the instant polypeptide of SEQ ID NO: 2 are very widely variant. Even if the full length of SEQ ID NO: 2 is utilized in a said

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method, all polypeptides encompassed by the limitation of at least 90% identity to the SEQ ID NO: 2 are very widely variant genus. As such, the disclosure of one representative species of method utilizing the polypeptide of SEQ ID NO: 2 is insufficient to be representative of the attributes and features of all species encompassed by the claimed genus of a polypeptide. Given the lack of description of a representative number of species, the specification fails to sufficiently describe species to represent the correlation between the structure and function of claimed genus, claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

12. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for a method for screening a compound capable of promoting or inhibiting the transcription-suppressing activity of SEQ ID NO: 2 as potentiated through the cAMP responsive element (CRE) and the promoter presented in the vector pTAL-CRE, which is manufactured by Clontech, does not reasonably provide enablement for said method for screening a compound promoting or inhibiting any activity of SEQ ID NO: 2, or the said method comprising the utilization of any polypeptide encompassed by the scope of the Claim 34 as described above.

The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use of the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is

required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated based on quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The nature of the invention: The claim 34 is drawn to a method for screening a compound capable of promoting or inhibiting the activity of a polypeptide SEQ ID NO: 2 comprising method steps of: allowing an expression vector and reporter gene under cAMP responsive element (CRE which is from pTAL-CRE, manufactured by Clontech) to contact with a test compound; and detecting the transcription activity of the reporter gene, wherein the expression vector encoding the polypeptide of SEQ ID NO: 2.

The breadth of claims: Claim 34 is drawn to a genus of method comprising utilization of any polypeptide having any degree of identity by the broad and reasonable interpretation of "substantially identical" to SEQ ID NO: 2 for screening a compound that changes any activity of SEQ ID NO: 2. The said polypeptide includes as small as any two consecutive amino acids (i.e. sequence) or a sequence with any number of amino acid residues having 90% identity compared to a corresponding SEQ ID NO: 2. The said polypeptide also includes all possible two consecutive amino acids encoded by a DNAs [i.e., any possible 6 consecutive nucleotide (the hexamer)] because any hexamer is capable of hybridizing to the SEQ ID NO: 1 under a certain condition. Optionally, the method above comprising utilization of said genus polypeptide which has an activity of regulating the transcription of any gene that is under control of any cAMP responsive element given the broadest and reasonable interpretation of Claim 34.

The amount of direction provided by the inventor and The existence of working examples: Applicants teach one screening method of utilizing the polypeptide SEQ ID NO: 2, regulating the transcription of a luciferase reporter gene under the cAMP responsive element from the vector pTAL-CRE (see Example 5, manufactured by Clontech) which is encompassed by the scope of instant claim.

The state of the prior art; The level of one of ordinary skill; and The level of predictability in the art: The prior art by Zhou et al. disclose a method of utilizing a human cAMP-Responsive Element (1999, Archives of Biochemistry and Biophysics, vol. 371, p. 179-190). The prior art by Park et al. (1993, The journal of Biological Chemistry, vol. 268, p. 613-619) also disclose a method steps utilizing the polypeptide which binds

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and effects the cAMP Regulatory Element in transcription of the phosphoenolpyruvate carboxykinase gene fused with reporter gene. However, the specification and prior arts fail to disclose direction or guidance on how to make and use of a method comprising any polypeptide encompassed by the instant claim having as small as any two consecutive amino acids (i.e. a sequence) or a sequence with any number of amino acid residues having 90% identity compared to a corresponding SEQ ID NO: 2, or all possible two consecutive amino acids encoded by a DNA sequence(s) [i.e., any possible 6 consecutive nucleotide (any hexamer) for modulating any activity of corresponding polypeptide, and optionally, the method above comprising utilization of said genus polypeptide which has an activity of regulating the transcription of any gene that is under control of any cAMP responsive element given the broadest and reasonable interpretation of Claim 34. Thus, the specification and prior art fail to describe how to make and use the claimed genus method sufficiently. Therefore, it is unpredictable for a method of utilizing any polypeptide encompasses by the claim, modulating any activity, or optional regulating transcription activity of any gene under the control of any cAMP responsive element encompassed by the very broad genus claims for screening a compound capable of promoting or inhibiting the activity of claimed polypeptides as described by the instant claim. For all of the above reason, it would require undue experimentation necessary for one skilled in the art to make and use the full scope of claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by reference by Park et al. (1993, The Journal of Biological Chemistry, vol. 268, p. 613-619).

Claim 34 is drawn to a method for screening a compound capable of promoting or inhibiting the activity of a polypeptide comprising method steps of: allowing an expression vector and reporter gene under a cAMP responsive element (CRE) to come into contact with a test compound; and detecting a change in activity of the polypeptide, wherein the vector encoding the polypeptide has at least 90% homology to a polypeptide that is substantially identical to SEQ ID NO: 2 or a polypeptide encoded by the cDNA capable of hybridizing to the nucleotide sequence of SEQ ID NO: 1.

Park et al. teach a method of utilizing a HepG2 cells transfected with DNA comprising PEPCK-CAT vector, the expression vector for C/EBP α , C/EBP β or CREB, and Rous sarcoma virus- β -galactosidase (see bottom left column, p. 620). The phosphoenolpyruvate carboxykinase (PEPCK) fused with CAT reporter gene was assayed by using [3 H]chloramphenicol and butyryl-CoA and the xylene phase extraction method (see bottom left column, p. 620). Park et al. teach that "C/EBP β stimulated transcription primarily through the cAMP-responsive element" (see Abstract, lines 10-11) and "CREB also bound to the CRE and stimulated transcription of a PEPCK-CAT vector" (see Abstract, bottom). The CREB of Park et al. meets the limitation of having

"at least 90%" identity to a "substantially identical" polypeptide SEQ ID NO: 2. The DNA from the vector containing CREB vector hybridizes to the instant SEQ ID NO: 1. The method steps of Park et al. teach utilization of CREB (which meets the limitation of the polypeptide encompassing any polypeptide sequence as described above) modulating the transcription activity of PEPCK-Cap reporter gene under the control of CRE in the presence of β -galactosidase (which meets the broadest and reasonable interpretation of limitation "testing compound"); allowing CREB and PEPCK-Cap vector in the presence of β -galactosidase; and detecting a change of activity of the polypeptide CREB using CAT reporter assay comprising the [3 H]chloramphenicol, butyryl-CoA and the xylene phase extraction method (see bottom left column, p. 620). Thus, the method steps of Park et al. teach all method steps having the limitations of Claim 34.

14. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by reference by Zhou et al. (1999, Archives of Biochemistry and Biophysics, vol. 371, p. 179-190).

Claim 34 is drawn to a method as described above.

Zhou et al. teach a method of transfecting and culturing a SK-BR-3 cells comprising a pUMSVOCAT vector (see Bottom of left column, p. 182) with genes as shown in top of Figure 2A wherein the genes are a Exon II region of human aromatase gene, a CAT (a reporter gene), a promoter 1.3 containing a cAMP-responsive element in the presence of a forskolin (see bottom, left column, p. 181). The forskolin of Zhou et al. would be capable of affecting the aromatase activity under a certain condition. Zhou et al. teach a method steps of assaying the change of aromatase activity by the

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increase in the total aromatase mRNA (see middle of left column, p. 182); thus, meets the limitation of detecting an activity of promoting or inhibiting the activity of the polypeptide as evidenced by the results of Zhou et al.'s teaching "as shown in Fig. 2A, after treatment with 20 uM of forskolin for 24 h, a four- and five-fold increase over the basal levels was detected in SK-BR-3 cells transfected with pUMS-104/+129CAT and pUMS-68/+129CAT plasmid" (see bottom right column, p. 182). The aromatase of Zhou et al. meets the limitation of having at least 90% homology to a polypeptide comprising amino acid sequence that is substantially identical to SEQ ID NO: 2. Thus, the method of Zhou et al. teach a method comprising: allowing contact of the polypeptide aromatase and the CAP reporter gene under the control of CRE-like element inside the SK-BR-3 cell in the presence of a compound forskolin; thus, meeting all method steps of Claim 34.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim
April 9, 2007

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal line extending to the right.

**RICHARD HUTSON, PH.D.
PRIMARY EXAMINER**